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K000651

510(k) Premarket Notification
Neurological Embolization Coil System
COOK INCORPORATED

Safety and Effectiveness Information

Submitted By: Lisa Webb, RAC
Regulatory Affairs Coordinator
COOK INCORPORATED
925 South Curry Pike
P.O. Box 489
Bloomington, IN 47402
(812) 339-2235
February 25, 2000

Device: Trade Name: Detach 11® and Detach 18®

Proposed Classification Name: Neurological Arterial Embolization Device

Predicate Devices:

Detach 11®/18® is similar in terms of intended use, materials of construction and technological characteristics to the predicate devices reviewed: Detach 11®/18® for peripheral use, the Embolization Coil Positioner Set, Hilal Embolization Microcoils™, the Vascular Occlusion System and the Guglielmi Detachable Coil®.

Device Description

This embolization coil system is supplied sterile and is intended for one time use. The device is comprised of an introducer system with a premounted detachable embolization coil. The embolization coil is deployed when the interlocking threads between the coil and the delivery wire are "unscrewed" by turning the delivery wire counterclockwise.

The introducer system consists of a delivery wire and a delivery wire inserter. The delivery wire inserter consists of a plastic delivery wire holder with the delivery wire and a cannula inserter containing the coil. A Detach Locking Device is also needed to use the set. This part is sold separately because several coils can be delivered through one Detach Locking Device.

Substantial Equivalence

Several devices are currently marketed which are believed to be substantially equivalent to Detach11®/18®. These devices include Detach 11®/18®-peripheral use (COOK INC), Embolization Coil Positioner Set (COOK INC), Hilal Embolization Microcoils™ (COOK INC), Vascular Occlusion System (Cordis Endovascular Systems, Inc.), and Guglielmi Detachable Coil® (Target Therapeutics®). All devices are introduced via the percutaneous method of entry

using a catheter or microcatheter introducer.

The similar indications for use and technological characteristics of the Detach 11® and Detach 18® Embolization Coil Systems as compared to the predicate devices support a determination of substantial equivalency.

Test Data

Detach 11®/18® was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests were comprised of:

- Tensile tests: Detach 18®
- Tensile tests: Detach 11®
- Tensile tests: Detachable Coils
- Performance Test in a Microferret™ Catheter Mounted in a Phantom
- Clinical Trial

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for the additional indication: "embolization of arteriovenous malformations and other vascular lesions of the brain, spinal cord and spine."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 4 2000

Ms. Lisa Webb, RAC
Regulatory Affairs Coordinator
Cook Incorporated
P.O. Box 489
Bloomington, Indiana 47402-0489

Re: K000651
Trade Name: Neurological Embolization Coil System
Regulatory Class: III
Product Code: HCG
Dated: September 28, 2000
Received: September 29, 2000

Dear Ms. Webb:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its ~~toll-free~~ number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Premarket Notification
Neurological Embolization Coil System
COOK INCORPORATED

510(k) Number (if known): K000651 K000651

Device Name: Neurological Embolization Coil System

Indications for Use:

Arterial and venous embolization in the peripheral vasculature and embolization of arteriovenous malformations and other vascular lesions of the brain, spinal cord and spine.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use____
(Per 21 CFR 801.109)

for Mark N Melkerson
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000651